

10/650,174 filed 08/28/2003
Parce, et al.
Reply to Office Action of November 30, 2005

REMARKS/ARGUMENTS

Claims 1–28 are pending in the above-captioned application. Of these claims, claims 1–27 stand rejected, and claim 28 is withdrawn from consideration.

I. Election/Restrictions

Applicants confirm that they have elected to prosecute the invention of Group I. The election was made without traverse. To simplify prosecution of this case, Applicants are canceling claim 28, while retaining the right to pursue this claim in a divisional application. The cancellation of the non-elected claim does not necessitate an amendment to the inventorship.

II. Priority

Applicants thank the Examiner for confirmation that the instant application is granted the benefit of priority for 09/579,111 (now U.S. Patent No. 6,649,358) as well as provisional applications 60/155,259; 60/176,001; 60/176,093; and 60/191,784.

III. Information Disclosure Statement

Applicants thank the Examiner for review of the information disclosure statements filed on 08/28/2003.

IV. Specification

Applicants have reordered the first two paragraphs of the specification such that the reference to the prior applications is the first sentence of the specification. Applicants have also added the current status of prior application 09/579,111. Please see page 2 of this response. As stated in the specification as filed, the instant application is a divisional of prior application 09/579,111, which is related to 09/323,747. Because 09/323,747 was converted to a provisional application (60/155,259), no specific relationship to 09/323,747 (i.e., continuation, divisional, or continuation-in-part) may be claimed.

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V. Claim rejections under 35 U.S.C. § 102(b) as being anticipated by Yager et al. (US 5,716,852)

Claims 1, 3, 13–15, 18–20, 21, 23, and 27 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yager et al. (US 5,716,852). This rejection is respectfully traversed. “[F]or anticipation under 35 U.S.C. § 102, a single reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” MPEP § 706.02. “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, USPQ2d 1913, 1920 (Fed. Cir. 1989).

With regard to independent claim 1, at a minimum, Yager et al. do not teach flowing at least one second component or a set of second components through a first channel “wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment”; nor do Yager et al. teach “detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel.” Note that hereinafter the phrase “first component” is used as a shorthand reference for “at least one first component or a set of first components,” and the phrase “second component” is used as a shorthand reference for “at least one second component or a set of second components.”

Yager et al. teach flowing an indicator stream 70 and a sample stream 80. The Examiner states on page 5 of the Office action that the indicator of Yager et al. refers to Applicants’ claimed first component, and sample (analyte particles) refers to Applicants’ claimed second component. Yager et al. neither explicitly nor impliedly teach that the analyte particles of sample stream 80 diffuse ‘less than substantially across’ mixing channel 100. Applicants refer the Examiner to Fig. 2 of Yager et al., which clearly shows the analyte particles of sample stream 80 diffused entirely across flow channel 100. Note that indicator 70 is diffused entirely across flow channel 100 as well.

Analyte from sample stream 80 that diffuses into indicator stream 70 becomes bound to the indicator substance carried by indicator stream 70. Yager et al. teach detecting this bound, rather than unbound, indicator (first component). As can be seen in Fig. 3, and as is

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discussed in column 9, lines 2–19, specimen streams containing the indicator are continuously taken out of the flow channel at various locations for detection, the fluorescence intensity of each specimen stream indicating the amount of indicator bound to analyte in that particular specimen stream. As the specimen streams are taken from the side of the system into which indicator initially flows (from indicator stream inlet port 20), rather than from the side into which sample initially flows (from sample stream inlet port 30), the illustrated system is not suitable for detecting unbound analyte particles. Further, unbound analyte particles

By contrast, Applicants illustrate their recited limitation of detecting a signal that indicates “a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel” with reference to their Fig. 6. Because the second component does not diffuse entirely across first channel 600, unbound first component (ligand) 604 is detected using detector 606 after the unbound first component has exited first channel 600 into fifth channel 608.

Thus, Yager et al. do not teach every aspect of the claimed invention either explicitly or impliedly, nor do they show the identical invention claimed by Applicants in as complete detail as is contained in claim 1. Withdrawal of the rejection of claim 1 under U.S.C. § 102(b) as being anticipated by Yager et al. is, therefore, respectfully requested.

Claims 3, 13–15, 18–20, 21, 23, and 27 depend directly or indirectly from claim 1. Therefore, Applicants respectfully submit that these dependent claims are allowable for at least the same reasons as set forth herein with respect to claim 1. Withdrawal of the rejection of dependent claims 3, 13–15, 18–20, 21, 23, and 27 under U.S.C. § 102(b) as being anticipated by Yager et al. is also respectfully requested.

VI. Claim rejections under 35 U.S.C. § 102(e) as being anticipated by Wu et al. (US 6,221,677 B1)

Claims 1, 3, 13–15, 20, 23, and 27 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Wu et al. (US 6,221,677 B1). This rejection is respectfully traversed.

With regard to Applicants' independent claim 1, at a minimum, Wu et al. do not teach flowing at least one second component or a set of second components through a first

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channel "wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment"; nor do they teach detecting a final concentration of the first component that "remains unbound." The Examiner cites the competitive immunoassays method of Wu et al. and, on page 6 of the Office action, states that the reagent stream of Wu et al. containing antibodies bound to fluorescently labeled antigen refers to Applicants' claimed first component, and the sample stream containing native antigen refers to Applicants' claimed second component.

Nowhere do Wu et al. explicitly or impliedly teach the limitation that components of the sample stream diffuse "less than substantially across" the reaction channel. In column 2, lines 45–56, cited by the Examiner, Wu et al. teach that "the native [antigens] diffuse into the reagent stream and displace the fluorescently labeled antigens." Relative amounts of bound and displaced fluorescently labeled antigen are measured to indicate the amount of native antigen in the sample stream. To produce an accurate indication, the native antigens must diffuse entirely across the reaction channel and through the reagent stream. This is highlighted by Wu et al. in column 10, lines 12–46, which emphasizes allowing the reaction to "go to completion."

In the present example, in which the Examiner has referred fluorescently labeled antigens to Applicants' first component and native antigens to Applicants' second component, only the labeled antigens are detected. These labeled antigens are of two types: those bound to the antibodies and those displaced from the antibodies by native antigens. Neither of these types of antigens can be considered to have remained unbound as recited in Applicants' claim 1. As stated by Wu et al. in column 6, lines 30–34, (emphasis added) "The detection channel of this invention may be coupled to external detecting means for detecting changes in the reagent particles carried within the product stream as a result of contact with analyte particles." While native antigens that fail to displace labeled antigens from the antibodies may be considered to have remained unbound, Wu et al. do not teach detecting a signal that indicates a final concentration of these unbound and, therefore, unchanged native antigens.

Thus, Wu et al. do not teach every aspect of the claimed invention either explicitly or impliedly, nor do they show the identical invention claimed by Applicants in as complete detail as is contained in claim 1. Withdrawal of the rejection of claim 1 under U.S.C. § 102(e) as being anticipated by Wu et al. is, therefore, respectfully requested.

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Claims 3, 13–15, 20, 21, and 27 depend directly or indirectly from claim 1. Therefore, Applicants respectfully submit that these dependent claims are allowable for at least the same reasons as set forth herein with respect to claim 1. Withdrawal of the rejection of dependent claims 3, 13–15, 20, 21, and 27 under U.S.C. § 102(e) as being anticipated by Wu et al. is also respectfully requested.

VII. Claim rejections under 35 U.S.C. § 102(e) as being anticipated by Parce et al. (US 6,274,337 B1)

Claims 1–27 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Parce et al. (US 6,274,337 B1). This rejection is respectfully traversed.

With regard to Applicants' independent claim 1, at a minimum, Parce et al. do not teach flowing at least one second component or a set of second components through a first channel "wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment"; nor do they teach "detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel."

Parce et al. are silent with regard to a component diffusing "less than substantially across" a first channel. As shown in Figs. 2A and 2B, components flowing through main channel 110 extend fully across the channel.

Parce et al. are also silent with regard to detecting components that remain unbound after exiting from a first channel. At the top of page 8 of the Office action, the Examiner indicates main channel 110 is referred to Applicants' first channel. In Figs. 1 through 2B, detection window 116 is within main channel 110 and, therefore, components are not detected after exiting the channel. Only in Fig. 5, discussed in column 23, line 53, through column 24, line 56, does detection take place after material has exited from reaction channel 510, into separation channel 524, which includes a detection window. The material detected in separation channel 524, however, is not an unbound component but a "receptor/ligand complex" as specified in column 24, lines 47–52.

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Thus, Parce et al. do not teach every aspect of the claimed invention either explicitly or impliedly, nor do they show the identical invention claimed by Applicants in as complete detail as is contained in claim 1. Withdrawal of the rejection of claim 1 under U.S.C. § 102(e) as being anticipated by Parce et al. is, therefore, respectfully requested.

Claims 2–27 depend directly or indirectly from claim 1. Therefore, Applicants respectfully submit that these dependent claims are allowable for at least the same reasons as set forth herein with respect to claim 1. Withdrawal of the rejection of dependent claims 2–27 under U.S.C. § 102(e) as being anticipated by Parce et al. is also respectfully requested.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned attorney.

Respectfully submitted,

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Signed: